

# Serial Release - APHIS Dispositions and Release Criteria On Form 2008s

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Source Document: CVB-SOP-0032, *Processing Serial Records*

The table below outlines the possible Establishment Dispositions available on an APHIS Form 2008 and the corresponding APHIS Dispositions. Some dispositions authorize market release of a serial, while others prohibit shipment of the serial. In addition, the firm may submit requests to the Center for Veterinary Biologics (CVB) using the APHIS Form 2008. Based upon the firm request submission, APHIS may approve or deny these requests through the corresponding APHIS Disposition.

## I. Disposition Criteria

*\* Notates the Default Disposition by LSRTIS for the applicable Establishment Disposition.*

Establishment (Firm) Disposition	APHIS Disposition	Criteria for Selecting APHIS disposition (if needed)
Eligible for Release	Not to be Tested*	The serial was not tested by the CVB. This disposition authorizes market release.
	Tests Completed Satisfactory	The serial was tested by CVB and the results were satisfactory. This disposition authorizes market release. Note – refer to the Prelicense Establishment Disposition for prelicense serials.
	Tests Completed UNSATISFACTORY	The serial was tested by CVB and the results were unsatisfactory. Additional Release Criteria to be included as a part of the APHIS Form 2008 – “UNSATISFACTORY RESULTS – NOT TO BE RELEASED. Disposition to be made under the supervision of APHIS.” See CVB-WI-0091 for guidance on Unsatisfactory CVB testing. This disposition PROHIBITS market release.

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**Establishment  
(Firm)  
Disposition**

**APHIS Disposition**

***Criteria for Selecting APHIS  
disposition (if needed)***

	Other - Serial Released for Market	<p>The serial was tested by the CVB and the results were either a No Test (NT) or Inconclusive (I) with no reason to suspect that the serial does not meet requirements. The serial is released for marketing based on the firm's test results reported.</p> <p>This disposition authorizes market release.</p> <p>In these cases the serial release criteria drop down should be added if the laboratory has added this to the test report: <i>"There is no evidence that this serial is unsatisfactory. May be released for marketing based on firm's satisfactory testing"</i>.</p> <p>These should be sent back to Specialist Review for their review.</p>
	Other – Serial NOT RELEASED FOR MARKET	<p>There is reason to suspect the serial does not meet the requirements, either due to testing conducted by CVB that resulted in a No Test (NT) or Inconclusive (I) or other information received by CVB. This disposition PROHIBITS market release.</p> <p>In these cases the serial release criteria drop down should be added if the laboratory has added this to the test report: <i>"Other" then manually add "There is evidence that this serial is unsatisfactory. May not be released for marketing based xxx."</i></p> <p>These should be sent back to Specialist Review for their review.</p>
	Other - UNSATISFACTORY Based on Firms Results	<p>Information reported on the APHIS Form 2008 indicates the firm's test results were unsatisfactory or inconclusive. The serial does not meet the requirements for marketing.</p> <p>This disposition PROHIBITS market release.</p>

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<b>Establishment (Firm) Disposition</b>	<b>APHIS Disposition</b>	<b><i>Criteria for Selecting APHIS disposition (if needed)</i></b>
	Conditional Release Granted	A firm may request conditional release of a serial, based on the criteria listed in CVB-WI-0151. The request must be reviewed by a Specialist and approved by IC Management. There may be other conditions regarding the release of the serial. This disposition authorizes market release.
Destroyed by Firm	Destroyed By Firm Acknowledged *	Acknowledgement of an unreleased serial that has been destroyed by the firm. NOTE: It is not an intent to destroy. This does not apply to serials already released or just for inventory adjustment or expired.
Reprocess & Retest	Reprocessing & Retesting Approved *	Approval for a request to rebottle a serial in accordance with 9 CFR 114.18. Refer to CVB-WI-0106 for processing.
	Reprocessing & Retesting DENIED	Denial for a request to rebottle a serial in accordance with 9 CFR 114.18.
Other - Expiration Date Correction	Other – Expiration Date Correction Acknowledged *	Acknowledges the Firm's expiration date correction. This is not an extension of dating.
Other - Prelicense	Prelicense - Expired	A serial used to support the licensure of a product, may have been tested by CVB and the results were satisfactory, but expired prior to licensure. This disposition PROHIBITS market release. Refer to CVB-WI-0108 for processing prelicensing serials.
	Prelicense - Tests Completed Satisfactory	A serial used to support the licensure of a product, tested by CVB and the results were satisfactory. This disposition authorizes market release after licensure.

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**Establishment  
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Disposition**

**APHIS Disposition**

***Criteria for Selecting APHIS  
disposition (if needed)***

	Prelicense - Tests Completed UNSATISFACTORY	A serial submitted in support of licensure, tested by CVB and the results were unsatisfactory. See CVB-WI-0091 for guidance on Unsatisfactory CVB testing. However, CVB-IC will audit most of these based on CVB-WI-0108. This disposition PROHIBITS market release.
	Prelicense - Serial Release for Market	A serial submitted in support of licensure, tested by CVB and the results were either a No Test (NT) or Inconclusive (I) with no reason to suspect that the serial does not meet requirements. The serial is released for marketing based on the firm's test results reported. In these cases the serial release criteria should be added: "There is no evidence that this serial is unsatisfactory. May be released for marketing based on firm's satisfactory testing". This disposition authorizes market release after licensure.
Other - For Further Manufacture	Other – Release For Further Manufacture *	This disposition authorizes shipment of the material to another licensed or permitted establishment for further processing.
Other - Extension of Dating	Other – Extension of Dating Approved *	Approval for a request to extend dating of a serial in accordance with 9 CFR 114.14. Refer to CVB-WI-0117 and CVB-FRM-0099.
	Other – Extension of Dating Denied	Denial for a request to extend dating of a serial in accordance with 9 CFR 114.14.
Other - File for Information	Other – File for Information Acknowledged *	Information submitted to CVB on a serial or bulk material that already has an APHIS disposition. It may be at the request of CVB or additional information provided by the firm. May or may not impact marketability of the serial. This also may apply to stability testing requested by the CVB.

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<b>Establishment (Firm) Disposition</b>	<b>APHIS Disposition</b>	<b><i>Criteria for Selecting APHIS disposition (if needed)</i></b>
	Other - File for Information Tested Satisfactory	Information submitted to CVB on a serial or bulk material, usually related to a veterinary biologics investigation (VBI) and has been tested by CVB and the results were satisfactory. May impact marketability of the serial or use of the bulk in final product.
	Other - File for Information Tested UNSATISFACTORY	Information submitted to CVB on a serial or bulk material, usually related to a veterinary biologics investigation and has been tested by CVB and the results were unsatisfactory. Bulk tested required to be conducted by the CVB prior to final product submission is also submitted with this disposition. May impact marketability of the serial or use of the bulk in final product. See CVB-WI-0091 for guidance on Unsatisfactory CVB testing
Other - Inventory Correction	Other - Inventory Correction Acknowledged *	Acknowledges the Firm's inventory correction.
Other – Rebottling	Other - Rebottling Approved *	Approval for a request to rebottle a serial in accordance with 9 CFR 114.17. Refer to VSM 800.62 Also CVB-WI-0106
	Other - Rebottling DENIED	Denial for a request to rebottle a serial in accordance with 9 CFR 114.17.
Other - Subsequent Shipment	Other - Subsequent Shipment Approved *	A second or subsequent shipment of a serial that was previously imported under US Veterinary Biologics Permit for Sale and Distribution and was found suitable for marketing. This disposition authorizes market release. Refer to VSM 800.101
	Other - Subsequent Shipment DENIED	A second or subsequent shipment of a serial that was previously imported under US Veterinary Biologics Permit for Sale and Distribution that is unsuitable for market, either because of shipping errors,



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<b>Establishment (Firm) Disposition</b>	<b>APHIS Disposition</b>	<b><i>Criteria for Selecting APHIS disposition (if needed)</i></b>
		tests conducted by CVB, or other regulatory reasons. This disposition PROHIBITS market release.
Other - Transfer	Other - Transfer Approved *	Approval for a request to transfer all or partial inventory for a serial already released to the market to another code or serial Refer to CVB-WI-0147.
	Other - Transfer DENIED	Denial for a request to transfer all or partial inventory for a serial already released to the market to another code.
Other - Shorten Dating	Shorten Dating Approved *	Approval for a request to market a lyophilized or frozen serial that does not meet the titer required for release, but is above the titer required at end of dating. This meets the intent of regulatory flexibility since these products often times cannot be reprocessed to increase the potency titer. Typically, this is half-dating. This disposition authorizes market release. Refer to CVB-WI-0130. This is not to be used when firms short the dating due to exports or marketing reasons.
	Shorten Dating DENIED	Denial for a request to market a lyophilized or frozen serial that does not meet the titer required for release. This disposition PROHIBITS shipment.
Other – Outline of Production Change	Dependent on if testing is conducted or not – follow Eligible for Release. Not to be Tested most likely to be used.	When PEL has requested testing by the firm to confirm an Outline of Production change, the firm should indicate this by this disposition or remarks.
Other – Technology Transfer	Dependent on if testing is conducted or not – follow Eligible for Release. Not to be Tested most likely to be used.	When PEL has requested testing by the firm to confirm a technology transfer request, the firm should indicate this by this disposition or remarks.

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**II. Instances that a Second Stage 2008 is Processed**

Additional Information in conjunction with the Market Release Process – This is usually on the second or subsequent APHIS Form 2008 submitted in order to change or confirm a marketing disposition for a serial. In order to confirm the disposition or to change the disposition, the Specialist may request additional information. A new/revised APHIS Form 2008 must also be submitted for processing.

<b>Original APHIS Disposition</b>	<b>Revised or Confirmed APHIS Disposition</b>	<b>Explanatory Comment – included as a part of the APHIS Form 2008</b>
Other- UNSATISFACTORY Based on Firms Results	Other - Serial Released for Market	This rescinds the UNSATISFACTORY ACTION previously reported. Serial may be released..
Other- UNSATISFACTORY Based on Firms Results	Other - UNSATISFACTORY Based on Firms Results	This confirms the UNSATISFACTORY ACTION previously reported.  This disposition PROHIBITS shipment.
Tests Completed UNSATISFACTORY	Tests Completed UNSATISFACTORY	This confirms the UNSATISFACTORY ACTION previously reported. Disposition to be made under supervision of APHIS  This disposition PROHIBITS shipment.
Tests Completed UNSATISFACTORY	Tests Completed SATISFACTORY	This rescinds the UNSATISFACTORY ACTION previously reported. Serial may be released.
*Conditional Release Granted	Depends on CVB Test Status. Refer to the Eligible for Release Firm Dispositions.	This completes the conditional release granted by CVB.  Refer to CVB-WI-0151 for Conditional Release processing.
*Conditional Release Granted	Tests Completed UNSATISFACTORY	This rescinds the conditional release granted by CVB. Serial to be immediately recalled.

\* Does not require another submission of the APHIS Form 2008 from the firm.

**III. Release Criteria Needed**

When a serial has been submitted that is at the Bulk Stage, the following is added to the APHIS Form 2008:

- The APHIS Disposition may be granted as “File for Information.”
- The additional info to be added “**Bulk.**”

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IV. CVB-IC personnel (Usually IC Biologics Specialists) may choose to set Release Requirements for the manufacturers to perform specific actions as stipulations of release of a serial as part of Extension of Dating Requests, Reprocess and Retesting Requests, or other reasons. Examples of these release requirements may be additional potency testing near the end of dating, or submission of adverse events for the serial. See CVB-WI-0082, *Specialist Review Action within LSRTIS*, for examples on when to add these requirements.

V. [REDACTED]